IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Donald L. Wise, Debra J. Trantolo, David D. Hile, and Stephen A. Doherty

Serial No.: 10/613,975 Art Unit: 1642

Filed: July 3, 2003 Examiner: Not Yet Assigned

For: *VACCINES TO INDUCE MUCOSAL IMMUNITY*

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

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Pursuant to 37 C.F.R. §1.56 and 37 C.F.R. §1.97, Applicants submit an Information Disclosure Statement, including eight (8) pages of Form PTO-1449 and copies of the sixty-eight documents cited therein.

This Information Disclosure Statement is being filed under 37 C.F.R. § 1.97(b) prior to a first Office Action on the merits. It is believed that no fee is required with this submission. However, should a fee be required, the Commissioner is hereby authorized to charge any required fees to Deposit Account No. 50-1868.

U.S. Patents

Number	Issue Date	Patentee	Class/Subclass
5,429,822	07-04-1995	Gresser, et al.	424/426
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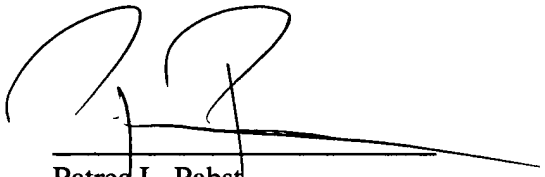
Remarks

This statement should not be interpreted as a representation that an exhaustive search has been conducted or that no better art exists. Moreover, Applicants invite the Examiner to make an independent evaluation of the cited art to determine its relevance to the subject matter of the present application. Applicants are of the opinion that their claims patentably distinguish over the art referred to herein, either alone or in combination.

Respectfully submitted,



Patrea L. Pabst
Reg. No. 31,284

Dated: October 28, 2003

HOLLAND & KNIGHT LLP
One Atlantic Center
1201 West Peachtree Street, N.E.
Suite 2000
Atlanta, Georgia 30309-3400
404-817-8473
FAX 404-817-8588
www.hklaw.com

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Filing Date	July 3, 2003
First Named Inventor	Donald L. Wise
Group Art Unit	1642
Examiner Name	
Attorney Docket Number	CSI 130

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U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	US Patent Document Number	Kind Code[2] (if known)	Name of Patentee or Applicant of Cited Document	Date of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		5,429,822		Gresser, et al.	07-04-1995	
		5,456,917		Wise, et al.	10-10-1995	

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		KLIMPEL, et al., "Anthrax toxin protective antigen is activated by a cell surface protease with the sequence specificity and catalytic properties of furin," *Proc. Natl. Acad. Sci., USA* 89: 10277-10281 (1992).	
		KLINMAN, et al., "Repeated administration of synthetic oligodeoxynucleotides expressing CpG motifs provides long-term protection against bacterial infection," *Infect. Immunol.* 67: 5658-5663 (1999).	
		KRIEG, et al., "CpG DNA induces sustained 1L-12 expression in vivo and resistance to *Listeria monocytogenes* challenge," *J. Immunol.* 161: 2428-2434 (1998).	
		KUPER, et al., "The role of nasopharyngeal lymphoid tissue," *Immunol. Today* 13(6): 219-224 (1992).	
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		LEE, et al., "Immunization of rhesus monkeys with a mucosal prime, parenteral boost strategy protects against infection with *Helicobacter pylori*," *Vaccine* 17: 3072-3082 (1999).	
		LEPPLA, et al., "Proteolytic activation of anthrax toxin bound to cellular receptors," in Bacterial protein toxins (Fehrenbach, et al., eds) pp. 111-112, Gustav Fischer: New York (1988).	
		LEPPLA, "Anthrax toxin edema factor: a bacterial adenylate cyclase that increases cyclic AMP concentrations in eukaryotic cells," *Proc. Natl. Acad. Sci. USA* 79: 3162-3166 (1982).	
		LITTLE & KNUDSON, "Comparative efficacy of *Bacillus anthracis* live spore vaccine and protective antigen vaccine against anthrax in the guinea pig," *Infect. Immun.* 52(2): 509-512 (1986).	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Complet If Kn wn	
Applicati n Number	10/613,975
Filing Date	July 3, 2003
First Named Inventor	Donald L. Wise
Group Art Unit	1642
Examiner Name	
Attorney Docket Number	CSI 130

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		LUNSFORD, et al., "Tissue distribution and persistence in mice of plasmid DNA encapsulated in a PLGA-based microsphere delivery vehicle," *J. Drug. Target.* 8(1): 39-50 (2000).	
		LUO, et al., "Synthetic DNA delivery systems," *Nature Biotech* 18: 33-37 (2000).	
		MCGHEE, et al., "The mucosal immune system: from fundamental concepts to vaccine development," *Vaccine* 10(2): 75-88 (1992).	
		MIKESELL, et al., "Evidence for plasmid-mediated toxin production in *Bacillus anthracis*," *Infect. Immun.* 39: 371-376 (1983).	
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		NEUTRA, et al., "Antigen sampling across epithelial barriers and induction of mucosal immune responses," *Ann. Rev. Immunol.* 14: 275-300 (1996).	
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		PEREZ, et al., "Poly(lactic acid)-poly(ethylene glycol) nanoparticles as new carriers for the delivery of plasmid DNA," *J. Control. Rel.* 75: 211-224 (2001).	

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		PERTMER, et al., "Gene gun-based nucleic acid immunization: elicitation of humoral and cytotoxic T lymphocyte responses following epidermal delivery of nanogram quantities of DNA," *Vaccine* 13(15): 1427-1430 (1995).	
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		SEDEGAH, et al., "Boosting with recombinant vaccinia increases immunogenicity and protective efficacy of malaria DNA vaccine," *Proc. Nat. Acad. Sci. USA* 95: 7648-7653 (1998).	
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		STOUTE, et al., "A preliminary evaluation of a recombinant circumsporozoite protein vaccine against *Plasmodium falciparum* malaria," *N. Engl. J. Med.* 336: 86-91 (1997).	
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		TRANTOLO, et al., "Delivery of vaccines by biodegradable polymeric microparticles with bioadhesion properties," *Proc. 5th World Congress, Chem. Eng.* (1996).	

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		VISSCHER, et al., "Biodegradation of and tissue reaction to 50:50 poly(DL-lactide-co-glycolide) microcapsules," *J. Biomed. Mat. Res.* 19: 349-365 (1985).	
		WANG, et al., "Simultaneous induction of multiple antigen-specific cytotoxic T lymphocytes in nonhuman primates by immunization with a mixture of four *Plasmodium falciparum* DNA plasmids," *Infect. Immunity.* 66(9): 4193-4202 (1998).	
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		WU & RUSSELL, "Nasal lymphoid tissue, intranasal immunization, and compartmentalization of the common mucosal immune system," *Immunol. Res.* 16(2): 187-201 (1997).	
		YEE, et al., "Loss of either $CD4^+$ or $CD8^+$ cells does not affect the magnitude of protective immunity to an intracellular pathogen, *Fancisella tularensis* strain LVS," *J. Immunol.* 157: 5042-5048 (1996).	

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